

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant: HATLESTAD et al. Examiner: Musselman, T.
Serial No.: 10/642,998 Group Art Unit: 3715
Filed: August 18, 2003 Docket No.: G UID.058PA

Confirmation No.: 2963 Customer No.: 51294

Title: SLEEP QUALITY DATA COLLECTION AND EVALUATION

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this paper is being electronically transmitted by EFS-WEB to the United States Patent and Trademark Office on April 19, 2010.

By: /Tracey Dotter/
Tracey Dotter

**APPELLANT'S STATEMENT IN SUPPORT OF
PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This statement is presented in compliance with the USPTO OG Notice of 12 July 2005 on New Pre-Appeal Brief Conference Pilot Program. Appellant requests a pre-appeal brief conference on the belief that claim rejections are clearly not proper and without basis.

Appellant believes that this submission only requires \$40.00 in Notice of Appeal fees because a \$500.00 Notice of Appeal fee was previously paid in connection with the filing of appeal on July 16, 2007 in this Application. (The appeal fee having since risen to \$540.00). The Application was subsequently taken out of appeal and a new rejection was issued by the Examiner without a final Board decision or other evidence of appellate level consideration. MPEP § 2104.01 provides for applying any previously paid appeal fees for filing a notice of appeal to a subsequent appeal as long as a final Board decision has not been made on the prior appeal. Authorization is given to charge Deposit Account No. 50-3581 (GUID.058PA) for this and any other necessary fees.

While Appellant would present more issues in an Appeal Brief, this request for Pre-Appeal review concerns certain deficiencies in the §103(a) rejection of independent claims 1 and 35 based on the combination of U.S. Patent No. 5,520,176 to Cohen (hereinafter “Cohen”), U.S. Patent No. 6,398,728 to Bardy (hereinafter “Bardy”), and “Aircraft Noise and Sleep Disturbance: Final Report” prepared by the Civil Aviation Authority London on behalf of the Department of Trade (hereinafter “CAA report”) as outlined in the Final Office Action mailed December 9, 2009 (hereinafter “Office Action”).

Appellant’s independent claim 1 recites:

sensing physiological information regarding at least one physiological condition related to sleep quality of a patient and indicative of patient sleep state;

sensing non-physiological information regarding at least one non-physiological condition that affects the sleep quality of the patient, the at least one non-physiological condition comprising an ambient condition external to the patient other than time, the physiological information and the non-physiological information sensed contemporaneously by respective sensors;

storing the physiological information and the non-physiological information in an implantable device; and

evaluating the patient’s sleep quality using both the physiological and non-physiological information by calculating a composite sleep quality metric as a function of the physiological and non-physiological information stored in the implantable device.

Independent claim 35 also concerns calculating a composite sleep quality metric as a function of contemporaneously sensed physiological and non-physiological information.

The rejection does not properly account for calculating a composite sleep quality metric as a function of physiological and non-physiological information, in the manner claimed. The Office Action appears to attempt to account for this aspect of the independent claims on Pages 2-3 in discussing the disparate sensing of a physiological parameter by Cohen and the collection of aircraft noise information in the CAA report. Specifically, the Final Office Action states that Cohen discloses collection and analysis of “measured physiological parameters” but that:

Cohen fails to teach of utilizing non-physiological parameters in the research process. However, a *research* study conducted by the Civil Aviation Authority London published in 1980 pertains explicitly to this very subject.

See page two, in the report summary, wherein it is described how aircraft noise was *measured* in various London neighborhoods on aircraft approach paths to the two main London airports in order to better understand how the noise interfered with the *sleep* processes of residents. It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate background noise measurements (i.e. non-physiological parameter measurements) in the manner of the 1980 CM *sleep quality research* project, into the *sleep research* System of Cohen, in order to expand the usefulness of the research system of Cohen to include cause and effect data pertaining to sleep problems.

It would have been obvious to one of ordinary skill in the art at the time of the invention to include such a distributed sensory and processing system, and particularly to have the processing occur internally to the patient, to improve the product in a manner as taught by Bardy, by allowing the device to process data and thus reducing the need for frequent external data analysis by a human (i.e. the device would transmit a derived measure, rather than simply raw data). (Pages 2-3, emphasis original).

Appellant respectfully disagrees with this basis for rejection and notes that Cohen, the CAA report, and Bardy do not teach or suggest calculating a composite sleep quality metric as a function of the physiological and non-physiological information. Disclosure of physiological data in Cohen and non-physiological data in the CAA report does not constitute a teaching or suggestion of calculating a composite sleep quality metric between them. Also, recognizing the convenience of a derived measure rather than raw data does not provide instruction concerning calculation of a *composite* sleep quality metric in the manner of the claims.

The calculation of a composite sleep quality metric from different physiological and non-physiological data sets is a material step that cannot be properly accounted for in a §103(a) rejection by mere reference to two different disclosures describing two different data sets and a statement about obviousness. This element of the claims is not disclosed by the references and the rejection is consequently insufficient and improper.

The independent claims further concern contemporaneous sensing of the physiological information and the non-physiological information for the composite sleep quality metric. There is no reason advanced for contemporaneous sensing of

the physiological parameters of Cohen and the airplane noise of the CAA report. In addition, Appellant respectfully notes that this aspect of the claims does not appear to be addressed or even mentioned in the Office Action. The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason why the claimed invention would have been obvious. (MPEP § 2142). For this further reason the rejection appears to be in error.

For each of the reasons discussed above, Appellant respectfully submits that the rejection fails to properly account for all elements of independent claims 1 and 35. Reversal of this rejection is therefore requested. In addition, reversal of the rejection of claims 2-5, 7-12, 14, 36-39, and 42-46 respectively depending therefrom is likewise requested.

The undersigned is with authority to prosecute this appeal on behalf of the Assignee.

Respectfully submitted,

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Date: April 19, 2010

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